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10/553,100	10/13/2005	Takayuki Oka	Q90338	2227
23373	7590	05/29/2008		EXAMINER
SUGHTRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			HAQ, SHAFIQUL	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,100	Applicant(s) OKA ET AL.
	Examiner SHAFIQU'L HAQ	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 2/14/08.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-8 and 10-28 is/are pending in the application.
- 4a) Of the above claim(s) 18-26 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-8,10-17,27 and 28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 October 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/13/05,12/29/05,2/3/06,8/14/06,9/15/06 & 7/27/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendments and remarks filed 2/14/08 is acknowledged and entered.

Response to Election/Restrictions

2. Applicants' election without traverse of Group I of claims 1-17 in response to Office Action of January 14, 2008 is acknowledged and entered. In the amendment filed February 14, 2008, claims 1 and 9 have been cancelled and new claims 27 and 28 have been added and the new claims 27 and 28 being dependent on claim 5 are directed to Group I embodiment. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, claims 18-26 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 2-8, 10-17, 27 and 28 are examined on merits.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-8, 10-14 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai *et al* (US 5,814,687) in view of Wang *et al* (US 5,283,079).

Kasai discloses magnetic polymer particles that are configured by incorporating a magnetic substance into an organic polymer material (see abstract and summary of invention) and the magnetic polymer particle being characterized in that the number average particle diameter of the magnetic polymer particles is generally 0.02-10 μ M (column 9, lines 24-25), which overlaps with the range of particle size of 1-30 nm of instant claim 2. Kasai also discloses that the magnetic substance is homogeneously dispersed throughout the center of the magnetic polymer particles (column 15, lines 12-15; column 6, lines 36-37 and column 8, lines 4-7 and 44-45), which reads on the phrase "magnetic substance being contained within a particle in a state of being dispersed" as recited in claim 2.

Kasai discloses different components ratio between the organic polymer content and the magnetic substance content (columns 4-9) and disclose preparation of magnetic polymer particles with different polymer magnetic substance ratios to obtain magnetic polymer particles having uniform particle with desired dispensability of magnetic substance, but fail to disclose a range of 0.3 or less for the absolute deviation in the content ratio of the magnetic material throughout the magnetic particles.

Wang discloses use of magnetic particle having uniform size distribution and magnetic content useful in immunoassays and for a wide variety of

Art Unit: 1641

biomedical applications (column 2, lines 8-10; claims 1, 9, 17 and 25). Wang also discloses that the magnetic particles can be optimized in terms of magnetic substance content for a wide variety of biomedical applications (column 5, lines 65-67).

Therefore, since it is common and known in the art of magnetic polymer particle to attempt to configure so that the magnetic particles have a uniform magnetic content to be useful for immunoassays and for a wide variety of biomedical applications (Wang), it would be obvious to one of ordinary skill in the art at the time of the invention to configure the magnetic polymer particle of Kasai so that the magnetic polymer particle has a uniform content of magnetic substance (and so uniform content ratio) throughout the magnetic polymer particles, as appropriate, with the expectation for use in a variety of biomedical applications. In addition, there is no critical technical significance to delimiting a range of 0.3 or less for the absolute deviation in the content ratio of the magnetic material throughout the magnetic particles in order to establish a reference for determining whether the magnetic material has a uniform content ratio and therefore, one of ordinary skill in the art could delimit a range of 0.3 or less for the absolute deviation in the content ratio of the carbonic element that constitutes the organic polymer substance and the metal element that constitutes the magnetic material by routine modifications, as appropriate. “[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” Application of Aller, 220 F.2d 454,456, 105 USPQ

Art Unit: 1641

223, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458,105 USPQ at 236-237.

With regard to claim 3, the claim refers to the product of claim 2, which is produced by a particular process. For product by process claim see MPEP 2113. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the magnetic particle of Kasai in view of Wang as described above would have the same characteristics as the magnetic substance-encapsulated particle of claim 2 (i.e. the product) that is obtained by the product by process claim of 3. However, as to the process, Kasai discloses oxidation of an iron compound in a polymerization process to prepare magnetic polymer particles (column 1, lines 45-51). As to claim 4, Kasai discloses magnetic polymer particles comprising iron (column 5, lines 60-65 and column 9, lines 5-15). As to claim 5, Kasai discloses magnetic polymer particle comprising more than 50% by weight of (meth)acrylate (see abstract) and the thus the main constituent of the organic polymer particle is polymer comprising an acrylic monomer. As to claim 6, Kasai discloses monomer glycidyl methacrylate (column 7, lines 14-

Art Unit: 1641

15). With regard to claim 7, Kasai discloses magnetic polymer particles comprising copolymer of acrylic monomer, vinyl monomer and monomer unit containing unsaturated carboxylic acid (column 3, lines 25-54) and disclose that the monomers include glycidyl methacrylate (column 7, lines 14-15) and styrene (column 5, lines 24-27). With regard to proportion of styrene monomer in the polymer (as claimed in claim 8), Kasai discloses different proportions of different monomers in the polymer composition (see polymer compositions of columns 3-7). However, as evidenced from the wide range (5-90% by weight) requirement, the proportion of the monomer units does not seem to be critical to the practice of the invention and a particular working condition can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art to discover an optimum value of a result effective variable. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable is a known process is ordinary within the skill of the art." Application of Boesch, 617 F.2d 272,276,205 USPQ 215, 218-219 (C.C.P.A. 1980).

Art Unit: 1641

With regard to claim 10, Kasai discloses that magnetic polymer particles including a magnetic substance can be prepared by polymerizing hydrophobic cross-linking monomers (column 2, lines 46-48). With regard to claim 11, polymer particles having a specific functional group (column 1, lines 45-47) and teaches that the magnetic polymer particle comprises ethylenically unsaturated carboxylic acid (column 4, lines 1-3). Further, Kasai discloses ethylene glycol dimethacrylate (column 7, line 20) as a component that constitutes the polymer, which is a bifunctional crosslinkable monomer and therefore, the polymer that is disclosed therein can be considered to be a crosslinked polymer. In addition, styrenesulfonate (column 7, lines 6-7) is used as the vinyl monomer that constitutes the polymer; therefore, it can be expected that sulfonic acid groups are present on the surface of the polymer in question. As to claim 12, Kasai discloses number average particle diameter of magnetic polymer particle is generally 0.02 to 10 μ M preferably 0.5 to 5 μ M (lines 24-26 of column 9), which overlaps with "average particle size of 0.05 to 1 μ M" of instant claim 12. As to claim 13, Kasai discloses that proportion os supermagnetic substance in the magnetic polymer particles is preferably 1-100 parts by weight, more preferably by 5-80 parts by weight by 100 parts by weight of acrylate polymer and a particularly preferred proportion of the supermagnetic substance is 10-60% parts by weight (column 7, lines 40-54), which overlaps with 0.1 to 50% by weight of the magnetic substance content of the magnetic substance-encapsulated particle of instant claim 13. As to claim 14, Kasai discloses that particle diameter of

Art Unit: 1641

supermagnetic substance constituting magnetic polymer particle is preferably 40-300Å (i.e. 4-30nm), more preferably 50-200 Å (i.e. 5-20nm) and particularly preferably 60-150 Å (i.e. 6-15 nm) (line 66 of column 5 to line 10 of column 6), which overlaps with particle size of magnetic substance of 2 to 10nm of instant claim 14. It is noted that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

With regard to claim 27, Kasai discloses that vinyl monomer unit (C) can be polymerized with monomers A (acrylic monomer) and B (monomer unit containing unsaturated carboxylic acid) and the monomer C may be ethylene glycol (meth)acrylate, diethylene glycol (meth)acrylate or polyethylene glycol (meth)acrylate (column 5, lines 24-36). Kasai does not disclose the number of ethylene oxide repeat in the polyethylene glycol (meth)acrylate but compounds differing regularly by the successive addition of the same chemical group (e.g., by -CH₂CH₂O- repeat groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) ((MPEP § 2144.08) and thus different number of repeat groups would be obvious absent unexpected results.

Art Unit: 1641

6. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai *et al* (US 5,814,687) in view of Wang *et al* (5,283,079) as described above and further in view of Noetzel *et al* (US 4,568,706).

See the above teaching of a magnetic substance of Kasai *et al* in view of Wang *et al*. Kasai further teaches that biologically active materials such as antibodies, antigens etc. can be combined with the magnetic polymer particles and either a chemical bonding method or a physical adsorption method can be used for immobilizing the biological materials (column 13, lines 53-67 and claim 8 of Kasai). Kasai *et al* further teaches that magnetic polymer of their invention can be used as a carrier of biologically active materials such a protein, nucleic acid, enzymes etc. (Abstract and column 14, lines 7-13).

Kasai *et al* however, fail to teach a linker for linking the biologically active substance to the carrier through a linker.

Noetzel *et al* disclose cross-linked bead polymer and teaches that the cross-linked bead polymer can be used as carriers of biologically active substance (column 6, lines 12-15) wherein a spacer (e,g, bifunctional linkers) is preferably used for linking the biologically active substance to the polymeric beads. Noetzel et al teach that preferable spacer include as those which introduce epoxide group such as ethylene glycol diglycidyl ether. (line 66 of column 8 to line 14 of column 9). Noetzel et al further discloses that polymers containing epoxide groups which thus obtained using the linkers have a

Art Unit: 1641

considerable higher activity than other products obtained direct polymerization of monomers containing epoxide groups (column 9, lines 30-35).

Therefore, given the fact that biologically active substance can be linked to polymer containing beads by use of a spacer (i.e. a linker), preferably with bifunctional ethylene glycol diglycidyl ether linker which introduces epoxide groups and given the fact that epoxide groups so introduced provides polymer containing epoxide groups that are considerably more reactive than polymer beads wherein functional groups are introduced by direct polymerization of monomers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a linker such as the ethylene glycol diglycidyl ether inker as though by Noetzel *et al* to link the biologically active substance to polymer encapsulated magnetic particle of Kasai *et al*, with the expectation of producing polymer encapsulated magnetic particle having epoxy group that are more reactive for linking the biologically active substance.

With regard to formation of covalent bond formation with antigen or an antibody (as claimed in claim 15 and 16), the epoxide group is capable of forming covalent bond with biologically active substance (column 3, lines 8-10) and with regard to claim 17, Noetzel *et al* as described above disclose ethylene glycol diglycidyl ether as a linker to link biologically active substance to polymeric substance.

7. Claims 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai *et al* (US 5,814,687) in view of Wang *et al* (5,283,079) as described

Art Unit: 1641

above and further in view of Ko *et al* (JP 2003012709 and pages 18-21 of STN search).

See the above teaching of a magnetic substance encapsulated particle of Kasai *et al* in view of Wang *et al*. Kasai further teaches that the magnetic particle of the invention can be used as a material for magnetic toner and magnetic inks (column 14, lines 7-13 of Kasai)

Kasai *et al* in view of Wang *et al* fail to teach that the magnetic substance encapsulated polymer comprises a compound represented by general formula (2) as claimed in claim 2.

Ko *et al* disclose microparticles comprising resins from vinylic and acrylic monomers wherein the resins include a monomer (see page 19 of STN search, RN 140651-97-4) having a formula that reads on the compound of formula (2). Ko *et al* further disclose that the microparticles having the resin composition can be used in applications as ink and ink-jet recording devices and the resin composition provides particle with good stability (see title and abstract and pages 18 of STN search).

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to include the monomers of Ko *et al* in the polymeric composition of Kasai *et al* with the expectation of providing magnetic substance particle with good stability useful in applications as ink, because Kasai *et al* envisioned using the magnetic particle as toner and as inks and Ko *et al* teaches that the polymeric composition provides good stability to the particles.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Examiner, Art Unit 1641